#2A
PATENT B
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8/7/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE DIVISIONAL APPLICATION OF:
William J. Curatolo, et al.

SERIAL NO.: **To Be Assigned (Division of 08/727,634)** : EXAMINER: **To Be Assigned**

FILED: **Herewith** : ART UNIT: **To Be Assigned**

FOR: **Controlled-Release Dosage Forms of Azithromycin**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Preliminary Amendment

In the matter of the divisional application filed herewith, please make the following changes to the application:

In the claims:

Please add the following new claims 72-124

72. A sustained release dosage form of azithromycin which meets the following in vitro criteria:

(1) $Q_{0.25} \leq$ 200 mg,
(2) $Q_1 \leq$ 500 mg,
(3) $Q_2 \leq$ 1000 mg,
(4) $Q_4 \leq$ 1500 mg, and
(5) $Q_6 \leq$ 2000 mg,

when said dosage form is tested in a USP rotating paddle apparatus, said apparatus being described in USP XXIII dissolution test chapter 711, and wherein the apparatus has paddles rotating at 50 rpm and contains 900 mL of pH 6.0 sodium dihydrogen phosphate buffer at 37°C;

and wherein, if said dosage form is a capsule, said buffer is implemented to contain 0.1 mg/mL of trypsin.

73. A dosage form as defined in claim 72, wherein said azithromycin is embedded in a matrix, which releases said azithromycin by diffusion.

74. A dosage form as defined in claim 73, wherein said matrix remains substantially intact during the period of drug release.

75. A dosage form as defined in claim 73, wherein said azithromycin is embedded in a matrix which releases said azithromycin by eroding.

76. A dosage form as defined in claim 75, wherein said matrix comprises hydroxypropyl methylcellulose.

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